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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,466	02/02/2001	Burton G. Christensen	P-087-R	7142

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THERAVANCE, INC.  
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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/776,466

Applicant(s)  
Christensen

Examiner  
David Lukton

Art Unit  
1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 19, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

A restriction is imposed, as set forth below. First, however, the following subgenera are defined:

- G1:**  $R^2$  must be the following, or contain the following:  $-R^a-Y-R^b(Z)_x$
- G2:**  $R^3$  (or  $R^{22}$ ) must be the following, or contain the following:  $-R^a-Y-R^b(Z)_x$
- G3:**  $R^4$  must be the following, or contain the following:  $-R^a-Y-R^b(Z)_x$
- G4:**  $R^5$  (or  $R^{23}$ ) must be the following, or contain the following:  $-R^a-Y-R^b(Z)_x$
- G5:**  $R^6$  must be the following, or contain the following:  $-R^a-Y-R^b(Z)_x$
- G6:**  $R^7$  must be the following, or contain the following:  $-R^a-Y-R^b(Z)_x$
- G7:**  $R^{12}$  (or  $R^{27}$ ) must be the following, or contain the following:  $-R^a-Y-R^b(Z)_x$
- G8:**  $R^{15}$  must be the following, or contain the following:  $-R^a-Y-R^b(Z)_x$

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Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1 and 17, drawn to compounds, limited to G1
2. Claims 1-6, 10, 11, 17-18, drawn to compounds, limited to G2
3. Claims 1, 2, 17-18, drawn to compounds, limited to G3
4. Claims 1-5, 10-12, 17-18 drawn to compounds, limited to G4
5. Claims 1, 2, 17-18 drawn to compounds, limited to G5
6. Claims 1, 2, 15-18 drawn to compounds, limited to G6
7. Claims 1, 2, 10, 17, 18 drawn to compounds, limited to G7

8. Claims 1-18 drawn to compounds, limited to G8
9. Claim 22, drawn to compounds
10. Claim 19, drawn to a method of using the compounds of Group 1
11. Claim 19, drawn to a method of using the compounds of Group 2
12. Claim 19, drawn to a method of using the compounds of Group 3
13. Claim 19, drawn to a method of using the compounds of Group 4
14. Claim 19, drawn to a method of using the compounds of Group 5
15. Claim 19, drawn to a method of using the compounds of Group 6
16. Claim 19, drawn to a method of using the compounds of Group 7
17. Claim 19, drawn to a method of using the compounds of Group 8

Claim 20 is not grouped., In the event that one of Groups 1-8 is elected, claim 20 will be joined with that group.

Claims 1-18 have been initially sequestered into each of eight different groups, depending on the position of the “-R<sup>a</sup>-Y-R<sup>b</sup>(Z)<sub>x</sub>” substituent. Moving this “-R<sup>a</sup>-Y-R<sup>b</sup>(Z)<sub>x</sub>” substituent from one position to another generates compounds which are distinguished on the basis of their antibiotic efficacy, their synthesis and their structure. One such regioisomer is not obvious over another. A different search would be required for each. In the event that one of Groups 1-8 is elected, and claims therein found allowable, the possibility

of rejoining one or more (of Groups 1-8) may be considered at that time.

In the event that one of Groups 1-8 is elected, and claims therein found allowable, claim 19 will be rejoined therewith for further examination.

Inventions 9 and {1-8} are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP section 806.04(b), 3rd paragraph), and the species are patentable distinct (MPEP section 806.04(h)).

In the instant case, the intermediate product is deemed to be useful for producing other glycopeptide antibiotics, and the inventions are deemed patentably distinct since there is nothing on the record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a

disclose specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific compound, with all substituent variables accounted for.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).


Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
DAVID LUKTON  
PATENT EXAMINER  
GROUP 1220